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PATENT
UMD 1-037CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of:
Kirin K. Chada et al.

Group Art Unit: 1633

Serial No.: 08/852,666

Examiner: Michael C. Wilson

Filed: 7 May 1997

For: **HMGI PROTEINS IN CANCER AND OBESITY**

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

RESPONSE PURSUANT TO 37 C.F.R. SECTION 1.143

Sir:

This Response pursuant to 37 C.F.R. Section 1.143 is in reply to the Examiner's Action dated 22 July 1998 in the above-identified patent application in which claims 1-40 were subjected to a restriction requirement. A Response to the 22 July 1998 Office Action was originally due 22 August 1998, without an extension of time. Applicants have petitioned concurrently herewith to extend the time for response to that Office Action for one month from 22 August 1998 up to

CERTIFICATE OF MAILING PURSUANT TO 37 C.F.R. SECTION 1.8

I hereby certify that this correspondence is being deposited, pursuant to 37 C.F.R. Section 1.8, with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this 14th of September, 1998.

By Richard R Muccino 14 Sept 98
Richard R. Muccino date
Reg. no. 32,538
Attorney for Applicant(s)

and including 22 September 1998 and have paid the required fee pursuant to 37 C.F.R. Sections 1.136(a) and 1.17. Accordingly, this Response is being timely filed.

Applicants request that the Examiner consider the following Response and withdraw the pending restriction requirement.

RESPONSE

The Examiner has objected to the declaration which claims the benefit under 35 U.S.C. 120. In accord with the Examiner's request, applicants have filed concurrently herewith a new declaration claiming the benefit of application serial no. 08/679,529.

The Examiner states that the specification fails to comply with the sequence rules because the claims do not contain Sequence ID numbers. Applicants do not understand which claims the Examiner is referring to since none of the claims contain sequences.

The Examiner has required restriction of the claims in the present application pursuant to 35 U.S.C. Section 121. Specifically, the Examiner states that restriction to one of the following groups is required.

I. Claims 1-5, and 39-40, drawn to a model for disease, specifically transgenic mammals with an inactivated HMGI, classified in class 800, subclass 2.

II. Claims 6-12, 18, and 20-22, drawn to methods for treating obesity by breeding a mammal with an inactivated HMGI gene, classified in class 435, subclass 172.3.

III. Claims 6-13, 17-19, 23-26, and 30-32, drawn to a method for treating obesity by reducing the bioactivity of HMGI by administering antisense molecules, classified in class 514, subclass 1 +.

IV. Claims 6-12, 14, 15-19, 23-25, 27-28, and 30-32, drawn to a method for treating obesity by inhibition of the DNA binding activity of HMGI, classified in class 435, subclass 172.3.

V. Claims 6-12, 16-19, 23-25, and 29-32, drawn to a method for treating obesity by inhibition of the protein:protein interactions of HMGI protein, classified in class 514, subclass 12.

VI. Claims 33-35, drawn to a method for screening compounds' ability to inhibit HMGI activity in vitro by determining their binding affinity, classified in class 435, subclass 7.1.

VII. Claims 36-38, drawn to a method of screening compounds' ability to inhibit HMGI activity in vitro by using transfected cells, classified in class 435, subclass 29.

The Examiner states that inventions I and II are related as product and process of use. The Examiner maintains that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). The Examiner concludes that in the instant case, the transgenic mice can be assay systems or models for HMGI lack of expression.

The Examiner states that inventions I and III are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not

disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner concludes that in the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms and the method of invention III is for treating obesity by inhibiting HMGI expression by antisense technology. The Examiner asserts that the protocols for making the mammal and the protocols for administering antisense molecules are materially different and separate. The Examiner argues that in making the mammal, the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo, and in the method of treating obesity, antisense molecules are administered to a developed mammal, thus, the inventions are distinct and separate.

The Examiner states that inventions I and IV are unrelated. The Examiner maintains that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The Examiner asserts that in the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms and the method of invention IV is for treating obesity by inhibiting the DNA binding activity of HMGI. The Examiner maintains that the protocols for making the mammal and the protocols for inhibiting the DNA binding activity of HMGI are materially different and separate, i.e., in making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo and in treating obesity, a compound is administered to a

developed mammal. The Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions I and V are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms and the method of invention V is for treating obesity by inhibiting the protein:protein interaction of HMGI protein. The Examiner concludes that the protocols for making the mammal and the protocols for inhibiting the protein:protein interaction of HMGI protein are materially different and separate, i.e., in making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo and in the method of treating obesity, a compound is administered to a developed mammal. The Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions I and VI are unrelated. The Examiner maintains that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms while the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner

maintains that the protocols for making the mammal and the protocols for screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e. in making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions I and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner maintains that the protocols for making the mammal and the protocols for screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e., in making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions II and III are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene and the method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology. The Examiner contends that protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and by inhibiting HMGI expression by antisense technology are materially different and separate, i.e., the protocol of invention II is breeding a developed mammal with an inactivated HMGI gene and in invention III, the protocol is administering antisense molecules to a developed mammal. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions II and IV are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene and the method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by

breeding a mammal with an inactivated HMGI gene and by inhibiting the DNA binding activity of HMGI are materially different and separate, i.e., the protocol of invention II is breeding a developed mammal with an inactivated HMGI gene and in invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. Thus, The Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions II and V are unrelated. The Examiner maintains inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner maintains asserts that in the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene and the method of invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate, i.e. the protocol of invention II is breeding a developed mammal with an inactivated HMGI gene and in invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions II and VI are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or

they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene and the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and for a method of screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e. the protocol of invention II is breeding a developed mammal with an inactivated HMGI gene and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions II and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that in the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and for a method of screening compounds' ability to inhibit HMGI activity in vitro are materially different and

separate, i.e., the protocol of invention II is breeding a developed mammal with an inactivated HMGI gene and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, The Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions III and IV are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that the method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology and the method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and by inhibiting the DNA binding activity of HMGI are materially different and separate, i.e. in invention III, the protocol is administering antisense molecules to a developed mammal and in invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. The Examiner concludes that the compound, reagents, dosages, composition of delivery, and route of delivery are different for each method and thus, the inventions are distinct and separate.

The Examiner states that inventions III and V are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not

disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that the method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology and the method of invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate, i.e. in invention III, the protocol is administering antisense molecules to a developed mammal and in invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. The Examiner concludes that the compound, reagents, dosages, composition of delivery, and route of delivery are different for each method and thus, the inventions are distinct and separate.

The Examiner states that inventions III and VI are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that the method of invention III is to a method of treating obesity in vivo by inhibiting HMGI expression by antisense technology and the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and for a method of screening compounds'

ability to inhibit HMGI activity in vitro are materially different and separate, i.e. in invention III, the protocol is administering antisense molecules to a developed mammal and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions III and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner asserts that the method of invention III is to a method of treating obesity in vivo by inhibiting HMGI expression by antisense technology and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner contends that the protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and for a method of screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e. in invention III, the protocol is administering antisense molecules to a developed mammal and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions IV and V are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation' or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner contends that the method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI and the method of invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The Examiner asserts that the protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate, i.e., in invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI and in invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. The compound, reagents, dosages, composition of delivery, and route of delivery are different for each method. The Examiner concludes that the compound, reagents, dosages, composition of delivery, and route of delivery are different for each method and thus, the inventions are distinct and separate.

The Examiner states that inventions IV and VI are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner contends that the method of invention IV is to a method of treating obesity in vivo by inhibiting the DNA binding activity of

HMGI and the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner asserts that the protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and for a method of screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e. in invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions IV and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner contends that the method of invention IV is to a method of treating obesity in vivo by inhibiting the DNA binding activity of HMGI and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner asserts that the protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and for a method of screening compounds' ability to inhibit HMGI activity in vitro are materially different and separate, i.e. in invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI and in the method of screening compounds' ability to inhibit HMGI activity in vitro, the HMGI gene and a reporter gene are transfected

into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions V and VI are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner contends that the method of invention V is to a method of treating obesity in vivo by inhibiting the protein:protein interaction of HMGI protein and the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro. The Examiner asserts that the protocols, reagents and techniques for a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate, i.e. in invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein and in the method of screening compounds' ability to inhibit HMGI activity *in vitro,* the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions V and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04,

M.P.E.P. §808.01). The Examiner contends that the method of invention V is to a method of treating obesity *in vivo* by inhibiting the protein:protein interaction of HMGI protein and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The Examiner asserts that the protocols, reagents and techniques for a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate, i.e. in invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein and in the method of screening compounds' ability to inhibit HMGI activity *in vitro,* the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that inventions VI and VII are unrelated. The Examiner maintains that inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. §806.04, M.P.E.P. §808.01). The Examiner contends that the method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity in vitro using a solid support and the method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity in vitro using a transfected cell. The Examiner asserts that the protocols, reagents and techniques for a method of screening compounds' ability to inhibit HMGI activity in vitro using a solid support and using a transfected cell are materially different and separate, i.e. in invention

VI, the protocol is HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured and in invention VII, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. The Examiner maintains that the apparatus, reagents, techniques, equipment and protocols are different for each method. Thus, the Examiner concludes that the inventions are distinct and separate.

The Examiner states that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The Examiner argues that because these inventions are distinct for the reasons given above and the search required for Groups I-VII are not required each other, restriction for examination purposes as indicated is proper. The Examiner concludes that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants elect to prosecute the claims of Group V; claims 6-12, 16-19, 23-25, and 29-32. Applicants traverse the Examiner's restriction requirements.

Applicants' invention, as defined in claims 1-5, pertains to a transgenic non-human mammal, the germ cells and somatic cells of which contain an inactivated HMGI gene sequence introduced into the mammal, or an ancestor of the mammal, at an embryonic stage.

Applicants' invention, as defined in claims 6-22, also pertains to a method for treating obesity in a mammal which comprises reducing the biological activity of HMGI genes in the mammal.

Applicants' invention, as defined in claims 23-32, also pertains to a method for regulating growth and development of adipose tissue in a mammal which comprises reducing the biological activity of HMGI genes in the mammal.

Applicants' invention, as defined in claims 33-35, also pertains to a method for screening candidate compounds capable of inhibiting HMGI biological activity which comprises the steps of (a) immobilizing a HMGI protein or a fragment thereof on a solid surface; (b) incubating the HMGI protein with a candidate compound under conditions which promote optimal interaction; and (c) measuring the binding affinity of the candidate compound to the HMGI protein or a fragment whereof; and (d) determining from the binding affinity which candidate compounds inhibit the HMGI biological activity.

Applicants' invention, as defined in claims 36-38, also pertains to a method for screening candidate compounds capable of inhibiting HMGI biological activity which comprises the steps of (a) transfecting into a cell a DNA construct which contains a reporter gene under control of an HMGI protein-regulated promoter; (b) administering to the cell a candidate compound; (c) measuring the levels of reporter gene expression; and (d) determining from the levels of reporter gene expression which candidate compounds inhibit the HMGI biological activity.

Applicants' invention, as defined in claims 39-40, also pertains to a mammal whose genome does not encode for both the functionally active leptin gene and the functionally active HMGI genes.

M.P.E.P. Section 803 states that there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent ... or distinct as claimed; and

(2) There must be a serious burden on the Examiner if restriction is not required...(emphasis added, citations omitted).

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions, M.P.E.P. Section 803. Applicants contend that the search and examination of the present application can be made without serious burden and request the Examiner to examine it on the merits. For example, groups II, IV, VI, and VII are all classified in Group 435. Groups III and V are all classified in Group 514.

Hence, applicants' product claims and method claims for preparing and using the product are not distinct inventions and restriction is not proper. In view of the foregoing Response, applicants request reconsideration pursuant to 37 C.F.R. Section 1.143 of the Examiner's position requiring restriction so that all of the claims can be examined in this single application thus helping to expedite prosecution of this application.

Applicants request the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments which might be most expeditiously handled by a telephone conference. Applicants' attorney authorizes the Examiner to charge Deposit Account 13-4822 if there are any additional charges in connection with this Response.

Respectfully submitted,
Kirin K. Chada et al.

By Richard R Muccino

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